Complete Summary

GUIDELINE TITLE

Safe site invasive procedure - non-operating room. Health care protocol.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Safe site invasive procedure -- non-operating room. Health care protocol. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Sep. 32 p. [5 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Any disease or condition requiring an invasive, high-risk non-surgical procedure performed outside of the operating room

GUIDELINE CATEGORY

Evaluation
Management
Prevention

CLINICAL SPECIALTY

Anesthesiology
Emergency Medicine

Internal Medicine
Nursing
Pediatrics
Preventive Medicine
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To eliminate wrong site, side, patient or procedure events when performed outside of the operating room
- To improve adherence with the key components of the Safe Site Invasive Procedure – Non-Operating Room protocol

TARGET POPULATION

Patients of all ages having any type of inpatient or outpatient invasive, high-risk non-surgical procedure performed in the clinic, procedural area, emergency department, or at a patient's bedside

INTERVENTIONS AND PRACTICES CONSIDERED

1. Pre-procedure evaluation and communication
2. Pre-procedure verification of patient, procedure, and site
3. Site marking with provider initials if indicated
4. Hard stop if necessary
5. Time out process with all staff members actively involved
6. Intra-procedure pause when indicated

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search of clinical trials, meta-analyses, systematic reviews, or regulatory statements and other professional order sets and protocols is performed.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of individual research reports is assessed using a hierarchical rating system.

A. Primary Reports of New Data Collection

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Systematic review
- Decision analysis

- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Document Development

A workgroup consisting of 6 to 12 members that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, and an Institute for Clinical Systems Improvement (ICSI) staff facilitator develops each document. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups, hospitals or other organizations that are not members of ICSI.

The work group will meet for 3 to 4 three-hour meetings to develop the protocol. Under the coordination of the ICSI staff facilitator, the work group develops the algorithm and writes the annotations and literature citations. The literature is graded in the document based on the ICSI Evidence Grading System.

Once the final draft copy of the protocol is developed, the document is sent to the ICSI members for review and comment.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Review and Comment

The purpose of the review and comment process is to provide an opportunity for the clinicians in the member organizations to review the science behind the recommendations and focus on the content of the protocol. Review and comment also provides an opportunity for clinicians in each organization to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the protocol.

All member organizations are encouraged to provide feedback on protocols, however, responding to review and comment is not a criterion for continued membership within the Institute for Clinical Systems Improvement (ICSI).

Document Approval

Each protocol is approved by the appropriate steering committee. There is a steering committee for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each protocol based on:

- Member comments have been addressed reasonably.
- There is sufficient reason to expect that members will use the protocol with minor modifications or adaptations.
- Within the knowledge of the reviewer, the recommendations in the protocol are consistent with other protocols, regulatory and safety requirements, or recognized authorities.
- When evidence for a particular step in the protocol has not been established, the work group identifies consensus statements that were developed based on community standard of practice and work group expert opinion.
- Either a review and comment by members has been carried out, or within the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of review is not needed.

Once the document has been approved, it is posted on the ICSI Web site and released to members for use.

Document Revision Cycle

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. For documents that are revised on a 24-

or 36-month schedule, ICSI checks with the work group on an annual basis to determine if there have been changes in the literature significant enough to cause the document to be revised earlier or later than scheduled.

ICSI checks with every work group 6 months before the scheduled revision to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Literature Search

ICSI staff working with the work group to identify any pertinent clinical trials, meta-analysis, systematic reviews, or regulatory statements and other professional guidelines conduct a literature search.

Revision

The work group will meet for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

A second review by members is indicated if there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations.

If a review by members is not needed, the document goes to the appropriate steering committee for approval according to the criteria outlined above.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for safe site invasive procedure – non-operating room are presented in the form of a protocol and an algorithm with 22 components, accompanied by detailed annotations. An algorithm is provided for Safe Site Invasive Procedure – Non-Operating Room. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Clinical Highlights

- Patient identification and pre-procedure verification that include the procedure(s), site(s), laterality and level, and are confirmed with information on the consent form, medical record, diagnostic studies and discussion with the patient. *(Annotation #2)*
- The anesthesia practitioner will confirm the patient's identity, procedure and site prior to the administration of local or regional anesthesia. *(Annotation #2)*
- Procedure sites will be marked with the initials of the provider. The provider will confirm the patient's identity, procedure(s) and site(s)/site prior to initialing the site. For bilateral procedures, both sides will be marked. *(Annotation #4)*

- Multiple sites/digits in the same anatomic location are to be labeled on the informed consent documentation and marked on the patient in the same manner. *(Annotation #4)*
- Procedures involving the spine require site marking including position, laterality and general level. *(Annotation #4)*
- A Time Out will be performed just prior to the start of the procedure with active verbal confirmation by all the caregivers (and patient when able) involved in the care of the patient. *(Annotation #11)*
- If site determination is done at the time of the procedure using imaging, verbal confirmation should occur with team/patient and documentation should reflect use of imaging for site determination. *(Annotation #4)*
- An intra-procedure pause will be performed for all procedures that involve level, implants and/or laterality after an orifice or midline entry, and is confirmed by the care team through active oral participation. *(Annotations #14)*
- The Time Out procedure will be repeated for each different, anatomically distinct procedure. *(Annotation #11, 21)*
- When only one provider is present to perform the procedure, a Time Out to confirm the correct patient, procedure and site is appropriate. It is important to verify correct procedure and site with written documentation rather than relying on the patient. It is not necessary to engage others in this verification process if they would not otherwise be involved in the procedure.

Special Circumstances

Anatomical Variation: When a patient is known to have anatomical variation involving the procedure site, this information should be shared with the care team and additional steps taken to confirm the correct procedure site. This may include additional imaging or a second physician confirming the procedure site.

Outside Events: Events within a department, between departments or outside of an organization where the procedure is taking place and that can contribute to an error occurring. Strict labeling of specimens with a verification process is encouraged to reduce the potential of an error in a report, medical record documentation, or diagnostic study that could lead to a wrong site, wrong patient or wrong procedure.

Single Provider: There are invasive procedures that may involve only one provider. Even when there is only one person doing the procedure, an abbreviated Time Out to confirm the correct patient, procedure and site is appropriate. It is not necessary to engage others in this verification process if they would not otherwise be involved in the procedure.

Disruptive Behaviors: Intimidating and disruptive behaviors in health care organizations are not rare and can contribute to medical errors and poor patient satisfaction. It is imperative that organizations recognize and address any such behaviors allowing for a culture where the health care team functions optimally. All members of the health care team need to feel empowered to speak up, without fear of retaliation, when they identify a failed process or missed step that potentially threatens the delivery of safe patient care.

Safe Site Invasive Procedure – Non-Operating Room Algorithm Annotations

1. **Pre-Procedure Evaluation, Planning, and Communication**

   Verification of the consistency of all patient/procedural information (patient name, date of birth, medical record number, planned procedure, procedural site and laterality, as applicable) ideally begins at the point of scheduling.

   It is recommended that facilities establish a process to verify the consistency of all patient/procedural information upon receipt of procedure related documents. Potential sources include:

   - Procedural consent
   - Radiology reports
   - Pathology reports
   - Laboratory results
   - Procedural orders
   - Medical record copies
   - Physician referrals

   This could take the form of a checklist including the date and signature of the individual who receives and verifies that data are consistent on each document as received.

   All documentation should be provided by paper, fax, or electronic format (not by phone or verbal communication) except in emergent/urgent situations. Ideally, the patient should be provided the same information in hard copy form to bring to the appointments/procedure.

   Discrepancies in the consistency of patient name, date of birth, medical record number, planned procedure, procedural site or laterality should be:

   - Addressed immediately upon discovery
   - Guided by a process (e.g., unit supervisor informed)

   Planning for the procedure must not continue until discrepancy is resolved.

2. **Pre-Procedure Verification of Patient, Procedure, and Site**

   With the patient awake and aware if possible, the provider involved in the care of the patient will confirm the patient's identity, procedure and site by comparing the following:

   - Patient's identity, using two identifiers
   - Procedure name and site in the informed consent documentation
   - Information in the medical record
   - Diagnostic studies
   - Discussion with the patient/legal guardian

The ultimate responsibility for procedure and site verification lies with the provider performing the procedure.

See Appendix B, "Electronic Checklist of Pre-Procedure Assessment, Pre-Procedure Verification and Time Out" in the original guideline document for example of process documentation.

3. **Site Marking Required?**

   Exceptions to site marking include:

   - Emergency procedures
   - Midline structures
   - Single organ cases (cardiac procedures)
   - Teeth – Indicate operative tooth name(s) on informed consent documentation or mark the operative tooth (teeth) on the dental radiographs or dental diagram.
   - Premature infants for whom the mark may cause a permanent tattoo. No infants under the corrected gestational age of 38 weeks should be marked.
   - Interventional procedures where the insertion site is not predetermined (e.g., cardiac catheterization, peripherally inserted central catheters, central lines, arteriogram)
   - Procedures that enter through an orifice where the target organ is not associated with laterality (e.g., endoscopies, cystoscopy, laryngoscopy)
   - Site sensitive areas that may be marked above or lateral to the procedure site (e.g., scrotal sites will be marked on the groin area on the appropriate side of the body; breast sites will be marked on the breast or above the breast on the upper chest area)
   - Patient refusals – A defined procedure should be in place for documentation of a patient refusal of site marking.
   - Site marking is not required when the provider performing the procedure is in continuous physical presence with the patient from arrival for the procedure to conclusion of the procedure. All the essential patient identifiers, consents, medical records, x-rays and the necessary equipment must be present in the room, and the provider does not leave the room for any reason.

   When site marking does not apply, it should be noted as such in the procedure note/checklist according to individual facility policies.

4. **Site Marking with Provider Initials**

   The work group recommends the provider performing the procedure will verify the patient's identity, correct site and side of the procedure and will mark the procedure site using their initials with the patient involved, awake and aware, if possible. Prior to marking the procedure site location, the site will be confirmed through a review of:

   - Procedure name and side identification in the informed consent documentation

- Information in the medical record
- Diagnostic studies
- Discussion with the patient/legal guardian

The procedure site will be initialized using an indelible marker and will be visible when the patient is positioned, prepped and draped.

For multiple sites/digits on the same anatomic site – The procedures should be identified by an anatomical name on the informed consent documentation and the sites marked.

For procedures involving laterality – The informed consent documentation will indicate the laterality and the site will be marked accordingly.

Laterality also applies to procedures that have a midline or orifice entry but the internal target location involves laterality. The laterality for procedures entered via midline or orifice entry will be indicated on the informed consent documentation. See the definition for Site in the original guideline document for more information.

For bilateral procedures, both sites will be marked.

For procedures involving level (spine or ribs) – The informed consent documentation will indicate the laterality and level and the site will be marked in a way to indicate anterior or posterior, and general level (cervical, thoracic, lumbar, or rib number).

Radiologic image-guided procedures – It is understood that for some procedures the entry site or best approach is determined during the first phase of the procedure using special imaging, such as ultrasound, computed tomography scan and others. In cases such as these, verbal confirmation of final site selection should take place with team/patient, and documentation following the procedure should reflect the use of imaging to determine site.

6. **Hard Stop**

If any part of the verification process is not followed and/or a discrepancy is discovered, the procedure is halted and will not continue until the discrepancy is resolved.

Resolution of discrepancies will include:

- Reverification of patient identification
- Review of the information in the informed consent documentation
- Review of the medical record
- Review of diagnostic studies
- Discussion with the patient/legal guardian (if appropriate)

7. **Is Discrepancy Resolved?**

To consider a discrepancy resolved, confirmation of the correct procedure or site and side must include all forms of documentation. After the discrepancy has been resolved, the procedure and site verification process will be repeated.

Conversations related to resolution of discrepancies will be held in a quiet location, away from activity/distractions.

If the steps of the verification process cannot be completed and/or a discrepancy cannot be resolved, the procedure is cancelled and rescheduled.

10. **Repeat Verification Process**

If the provider or care team changes or the patient is moved, a repeat verification is required. Refer to verification components in Annotation #2, "Pre-Procedure Verification of Patient, Procedure and Site."

Structured Hand-Off

A structured hand-off is a standardized method of communication used to improve the exchange of information during patient care transitions. The purpose of a structured handoff is to promote patient safety by ensuring that critical pieces of information are conveyed to the next individual assuming care responsibilities including such things as critical test results, patient status, recent/anticipated changes in patient condition, plan of care/goals, what to watch for in the next interval of care, etc. This should be a process used by all caregivers and should be done during a patient transition from one caregiver to another. This should be done face to face to encourage discussion and questions.

11. **Active Oral Time Out Process**

The Time Out is to be performed immediately prior to the start of the procedure and is the final safety stop before the procedure is begun. The purpose of the Time Out is to ensure that the correct patient, site, side, positioning and procedure to be performed are all correctly verified. In addition, it is an opportunity to validate that any related images, equipment or implants are available.

The Time Out is to be initiated by the provider and includes active verbal acknowledgment by all members of the team. The scalpel, needle or other cutting/incising device is not to be handed to the provider until the Time Out has been completed. While it is desirable to actively include the patient in the Time Out, it is not always possible, particularly if the patient is under the influence of sedating medications or is otherwise unable to participate.

It is recommended that a visual memory aid be used to trigger the initiation of the Time Out. For example, a "Time Out" sign or towel can be used to cover the scalpel, needle or cutting/incising device as a reminder to conduct the Time Out. When one of these aids is used, it is important to hand it off

the sterile field at the conclusion of the Time Out so there is no potential for it to become retained in the patient.

Every Time Out must include the following standard elements:

- Patient identity, using a minimum of two identifiers
- Procedure(s) to be performed (including internal and/or external laterality, multiples and/or level)
- Patient positioning if not already verified
- Procedure side, site and/or level including visualization of the provider's initials if applicable
- As appropriate, imaging, equipment, implants or special requirements (e.g., pre-procedure antibiotic administration)

The provider may delegate the Time Out elements to the nurse or other member of the team, but the initiation of the Time Out should be the responsibility of the provider. The nurse or other team member may refer to the patient consent for the Time Out elements. However, prior to its use, the consent must have been validated against other documents, such as history and physical, radiology or pathology reports, progress notes, etc.

During the Time Out, each person in the procedure room must stop what he or she is doing and actively participate in the process. Involved staff may include the provider, resident, student, anesthesia, scrub, nurse and/or vendors whenever present. No individual is exempt from the process. Active participation requires each individual to state clearly and loudly that they agree with the elements of the Time Out. The scalpel, needle or other cutting/incising device is not to be handed to the provider until the Time Out has been completed. If a member of the team refuses to actively participate in the Time Out, the scalpel, needle or cutting/incising device is not handed to the provider until that individual is replaced and the Time Out completed.

Environmental distractions are to be eliminated as much as possible during the Time Out. For example, music is turned off, pagers are set on vibrate, talking other than participation in Time Out ceases and no staff are permitted to enter or exit the room. If during the Time Out an interruption or distraction occurs (pager goes off or an individual enters the room), the Time Out must be restarted.

See Appendix B, "Electronic Checklist of Pre-Procedure Assessment, Pre-Procedure Verification and Time Out" in the original guideline document for an example of process documentation.

Additional Time Outs are to be performed when there are two or more different procedures performed on the same patient during the same procedure period, whether or not the procedures involve a new procedure team. The process and elements of the Time Out as described above must occur prior to the start of the next procedure.

If the patient needs to be repositioned during the procedure and this repositioning affects the patient's presentation (i.e., the patient is turned prone), an abbreviated Time Out including the site, side, level and/or

visualization of the provider's initials will be conducted. The Time Out process will be the same as described above (e.g., elimination of distractions, active participation).

12. **Discrepancies?**

    If during the Time Out discrepancies between the consent, team members, imaging and/or equipment are discovered, the scalpel, needle or cutting/incising device is not to be handed to the provider until the discrepancy is resolved. It is important that the organization's administration and medical staff leadership team set the expectation that staff may, at any time, raise concerns or objections related to elements of the Time Out if they believe discrepancies do or may exist. Demeaning, derogatory or retaliatory statements and/or actions taken against one or more individuals as a result of a concern raised during the Time Out or any other part of the procedure are not to be tolerated. Organizations are encouraged to develop policies for managing such behavior.

14. **Are Any of the Following Procedures Performed? Midline or Orifice Entry/Spine or Procedures Involving Level/Implants**

    During the procedure, all members of the care team will actively participate in the intra-procedure pause.

    An intra-procedure pause will occur:

    For procedures involving internal laterality – procedures that have a midline or orifice entry. The provider will pause after the initial incision or entry and verbally indicate the internal laterality of the procedure target.

    For procedures involving level (spine or ribs) – procedures that involve levels will have pre- and intra-procedure imaging present in the procedure area. The provider will pause and confirm the target level of the procedure that was indicated by comparing the pre- and intra-procedure imaging.

    For implants – The provider will pause prior to receiving each item/implant and will confirm the following:

    - Implant specification/type/expiration date
    - Size
    - Laterality

17. **Multiple Procedures?**

    Additional Time Outs are to be performed when there are two or more different procedures performed on the same patient during the same procedure period, whether or not the procedures involve a new procedure team. When the same procedure is performed, at different sites, site confirmation only is required prior to performing the procedure. Examples to be considered are as follows:

- **Multiple procedures – different sites**:
    1. Biopsy of atypical lesions: face, scalp and right forearm
    2. Cryosurgery: verruca at right hand 3rd digit, left hand 4th and 5th digits, and left great toe
    3. Skin tag removal at right axilla, left axilla and beneath left breast
- **Different procedures - multiple sites**:

    1. Cryosurgery actinic keratosis: right cheek, nose, left ear, right forearm, right hand. Incision and drainage cyst at upper back, biopsy of atypical lesion right lower back
    2. Toenail removal at right great toe. Cryosurgery verruca at right heel. Biopsy atypical lesion at right leg
    3. Cryosurgery actinic keratosis at left arm, right arm, nose and left ear. Biopsy lesion at left cheek and dorsal left hand

21. **Time Out Verification Process Repeated Prior to Start of Next Procedure**

    Additional Time Outs are to be performed when there are two or more different procedures performed on the same patient during the same procedure period, whether or not the procedures involve a new procedure team. The process and elements of the Time Out must occur prior to the start of the next procedure. Refer to Annotation #11, "Active Oral Time Out Process."

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for Safe Site Invasive Procedure – Non-Operating Room.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate safe sit invasive procedures when performed outside of the operating room

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This health care protocol is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A health care protocol will rarely establish the only approach to a problem.
- This health care protocol should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for release, a member group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Priority Aims and Suggested Measures

Outcome Aim and Measure

1. Eliminate wrong site, side, patient or procedure events when performed outside of the operating room.

   Possible measures for accomplishing this aim:

   a. Wrong invasive or high-risk procedure events per month.
   b. Rate of wrong invasive or high-risk procedure events per month.
   c. Near misses reported per month.

Process Aim and Measure

2. Improve adherence with the key components of the Safe Site Invasive Procedure – Non-Operating Room protocol.

   Possible measures for accomplishing this aim:

   a. Percent of appropriate invasive procedure patients who had their site marked by the provider performing the invasive procedure.
   b. Percent of invasive procedure patients with documentation of verification of correct patient, site/side and procedure.
   c. Percent of cases in which a verbal, active Time Out is conducted by providers present prior to the start of the procedure.
   d. Percentage of invasive procedure patients who have had all required components of the Safe Site Invasive Procedure – Non-Operating Room protocol applied.

Note: All-or-none measures is a percentage determined by applying an all-or-none rule to multiple individual measures at the patient level.

Key Implementation Recommendations

The following system changes were identified by the protocol work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

1. Leadership support and a physician champion are absolutely essential for the successful implementation of this protocol.
2. To facilitate implementation of the Hard Stop concept, have your chief executive officer communicate to all staff and physicians his or her support for the institution of the Hard Stop.
3. Charter a team that consists of representatives from each department, area or clinic. This helps to ensure broader commitment as the work is moved across an organization, as well as cross-learning from the various experiences.
4. Create and implement a process that allows for the detection and management of disruptive and inappropriate behavior consistent with The Joint Commission's new leadership and national patient safety goals. This process should include education to all staff including physician regarding appropriate professional behavior and the development of policies and procedures.
5. Establish pre-procedure and post-procedure communication standards in the form of structured hand-offs.
6. Create a process that addresses how to monitor compliance and incorporate this monitoring process into an electronic system.
7. Develop a procedural checklist to document completion of each step and ensure that all elements of the protocol are completed.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm
Quality Measures

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Safe site invasive procedure -- non-operating room: percentage of wrong invasive or high-risk radiological procedure events outside of the operating room per month.
- Safe site invasive procedure -- non-operating room: percentage of appropriate invasive procedure patients who had their site marked by the provider performing the invasive radiological procedure.
- Safe site invasive procedure -- non-operating room: percentage of invasive procedure patients with documentation of verification of correct patient, site/side and procedure.
- Safe site invasive procedure -- non-operating room: percentage of cases in which a verbal, active Time Out is conducted by providers present with the patient prior to the start of the procedure.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Safe site invasive procedure -- non-operating room. Health care protocol. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Sep. 32 p. [5 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Sep

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: icsi.info@icsi.org; Web site: www.icsi.org.

SOURCE(S) OF FUNDING

The following Minnesota health plans provide direct financial support: Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, Metropolitan Health Plan, PreferredOne and UCare Minnesota. In-kind support is provided by the Institute for Clinical Systems Improvement's (ICSI) members.

GUIDELINE COMMITTEE

Committee on Evidence-Based Practice

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Marietta Farris, BSN (*Co-Work Group Leader*) (Fairview Health Services) (Nursing); Loree Kalliainen, MD, FACS (*Co-Work Group Leader*) (HealthPartners Regions Hospital) (Plastic Surgery); Kristy Enger, CMA (Chippewa County – Montevideo Hospital & Clinic) (Clinic); Neal C. Rucks, PA-C (Chippewa County – Montevideo Hospital & Clinic) (Clinic); Lisa Hurt, RN (Ridgeview Medical Center) (Home Health Services); Karin K. Fjeldos-Sperbeck, RN (Sanford Health) (Nursing); Stephanie Lach, MSN, MBA, RN (HealthPartners Regions Hospital) (Patient Safety & Quality); Karen Landeen, RN (Hennepin County Medical Center) (Radiology); Nancy Jaeckels (Institute for Clinical Systems Improvement)

(Measurement/Implementation Advisor); Janet Jorgenson-Rathke, PT (Institute for Clinical Systems Improvement) (Measurement/Implementation Advisor); Joann Foreman, RN (Institute for Clinical Systems Improvement) (Facilitator); Cally Vinz, RN (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The Institute for Clinical Systems Improvement (ICSI) has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals that participate in the development, revision and approval of ICSI documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee, and the Respiratory Steering Committee).

Participants must disclose any potential conflict and competing interests they or their dependents (spouse, dependent children, or others claimed as dependents) may have with any organization with commercial, proprietary, or political interests relevant to the topics covered by ICSI documents. Such disclosures will be shared with all individuals who prepare, review and approve ICSI documents.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Development and revision process for guidelines, order sets, and protocols. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Jun. 5 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

Also, the appendices of the original guideline document contain a checklist of pre-procedure assessment, pre-procedure verification, and Time Out.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on July 29, 2009.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 9/7/2009